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# Just What the Doctor Ordered—Or Was It?: Missouri Pharmacists' Duty of Care in the 21st Century

*Horner v. Spalitto*<sup>1</sup>

## I. INTRODUCTION

Recent studies have suggested that up to five percent of all prescriptions filled in hospitals contain errors.<sup>2</sup> Medical commentators have expressed concern that this figure may be even higher for outpatient prescriptions.<sup>3</sup> As a result of medication errors, patients suffer uncomfortable and even traumatic results in the form of “adverse drug events,” while the health care system incurs needless costs.<sup>4</sup> These adverse drug events are normally preventable,<sup>5</sup> and are

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1. 1 S.W.3d 519 (Mo. Ct. App. 1999).

2. According to the *British Medical Journal*, errors such as “choice of the wrong drug, dose, route, form, and frequency or time of administration” occur in up to five percent of all prescriptions. P.G. Nightingale et al., *Implementation of Rules Based Computerised Bedside Prescribing and Administration: Intervention Study*, 320 BRIT. MED. J. 750, 750 (2000). Those errors may be caused by (1) lack of access to drug-related information, (2) lack of access to the patient’s information (such as allergies or other medical conditions), (3) illegible handwritten prescriptions, and (4) lost or unavailable prescription sheets. *Id.*; see Timothy S. Lesar et al., *Factors Related to Errors in Medication Prescribing*, 277 JAMA 312, 312 (1997) (stating that factors related to errors include (1) improper calculations of dosage, (2) errors in decimal points, (3) similarly named medications, (4) problems with medication dosage forms, (5) the use of abbreviations, (6) “unusual routes of drug administration,” (7) complicated or uncommon dosage regimens, and (8) lack of information regarding the patient’s history).

In another study, the authors noted that some studies have reported that 15 to 18% of all discharge prescriptions contain errors, and that 38% of discharges receive one or more prescriptions containing errors. See Timothy S. Lesar et al., *Medication-Prescribing Errors in a Teaching Hospital: A 9-Year Experience*, 157 ARCHIVES OF INTERNAL MED. 1569, 1573 (1997) (noting also that adverse drug events occur in 6.5% of hospital admissions). The study further noted that pharmacists detect 1.4 to 3.2% of those errors. *Id.*

3. See, e.g., David P. Phillips et al., *Increase in U.S. Medication-Error Deaths Between 1983 and 1993*, 351 THE LANCET 643, 643 (1998) (stating that outpatient deaths attributable to medication errors increased by 8.48%, compared with 2.57% for inpatients). But see Cleone Rooney, *Increase in U.S. Medication-Error Deaths*, 351 THE LANCET 1656 (1998) (arguing that Phillips’s analysis is skewed because “medication errors” are not listed in death registrars, and that the accidental poisonings referred to may simply be caused by recreational drug overdoses).

4. According to the *Journal of the American Medical Association*, a well recognized medical journal, three of every one thousand patients admitted to the hospital will die because of an adverse drug event, and one out of every one thousand will suffer from a long-term disability due to an adverse drug event. See Robert A. Raschke et al.,

considered to be a current problem by hospital administrators and doctors alike.<sup>6</sup> Now, courts are beginning to recognize the problem, and have suggested a solution by adopting a heightened standard of care for pharmacists. In that respect, courts have begun to recognize that pharmacists are the last chance that the system has to correct itself, and that pharmacists are experts in pharmaceutical science and should be treated as professionals.<sup>7</sup>

Courts have not always treated pharmacists as professionals. Instead, pharmacists have traditionally been viewed as "order fillers" for the true professionals: the prescribing physicians. Until recently, Missouri adhered to that traditional view, requiring only that Missouri's pharmacists fill prescriptions accurately.<sup>8</sup>

Recently, however, the Missouri Court of Appeals for the Western District of Missouri recognized that pharmacists are professionals in their own right, and should be held to a higher standard. In *Horner v. Spalitto*, the court stated that pharmacists must act as would a reasonable pharmacist in the same or similar circumstances, a duty that may require more of them than correctly filling orders.<sup>9</sup> The implication for Missouri pharmacists is not only an expanded duty of care, but also a recognition of their professional status and place in Missouri's health care system.

*A Computer Alert System to Prevent Injury from Adverse Drug Events: Development and Evaluation in a Community Teaching Hospital*, 280 JAMA 1317, 1317 (1998). Adverse drug events may also cause up to 140,000 deaths per year in the United States. See David C. Classen, *Adverse Drug Events in Hospitalized Patients: Excess Length of Stay, Extra Costs, and Attributable Mortality*, 277 JAMA 301, 302 (1997) (noting further that "fatal ADEs are expected in approximately 0.31% of hospitalized patients in the United States"). The cost of each inpatient adverse drug event averages between \$1900 to \$5900. See Raschke, *supra*, at 1317.

5. See, e.g., Raschke, *supra* note 4, at 1318 ("From 28% to 56% of ADEs are preventable, and these are most commonly caused by errors in order writing.").

6. See, e.g., Richard Haugh, *To the Rescue*, 74 HOSP. & HEALTH NETWORKS 44, 48 (2000) (reporting the results of a survey that found that ninety-eight percent of hospital administrators believe drug errors are a significant problem in the health care system).

7. Some medical commentators argue that because pharmacists often detect errors in prescriptions, that they should take a more pro-active role in the prescribing process. See Lucian L. Leape et al., *Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit*, 282 JAMA 267, 267 (1999).

8. See generally *Kampe v. Howard Stark Prof'l Pharmacy, Inc.*, 841 S.W.2d 223 (Mo. Ct. App. 1992). As of June 30, 1999, Missouri had 6,608 licensed pharmacists. See Missouri Board of Pharmacy, Division of Professional Registration Statistics, available at <http://www.ecodev.state.mo.us/pr/pharmacy/statistics.htm> (visited Nov. 12, 2000).

9. See *Horner v. Spalitto*, 1 S.W.3d 519, 524 (Mo. Ct. App. 1999) ("We reject the suggestion in *Kampe* that the only functions which a pharmacist must perform to fulfill his duty is to dispense drugs according to a physician's prescription.").

## II. FACTS AND HOLDING

On September 21, 1994, Franklin Horner went to Anthony Spalitto's pharmacy in Kansas City, Missouri to have two prescriptions filled.<sup>10</sup> One prescription called for fifty 750 mg. doses of Placidyl, "a strong hypnotic drug"; one dose was to be taken every eight hours.<sup>11</sup> The second prescription was for fifty 10 mg. doses of Diazepam, "a central nervous system depressant," also directing Horner to take one dose every eight hours.<sup>12</sup>

In filling those two prescriptions, Peter Spalitto, the attending pharmacist, consulted a pharmaceutical manual entitled *Drug Facts and Comparisons*.<sup>13</sup> That manual stated that the normal dosage for Placidyl is "one 500 mg. dose or one 750 mg. dose before bedtime."<sup>14</sup> *Drug Facts and Comparisons* also "warned that the drug's effects were enhanced when it was combined with other central nervous system drugs, such as Diazepam."<sup>15</sup> Because Mr. Horner's physician had prescribed a higher dose of Placidyl than *Drug Facts and Comparisons* recommended, and had also prescribed Diazepam, Peter Spalitto called Mr. Horner's prescribing physician, presumably to confirm the prescription.<sup>16</sup> Peter Spalitto filled those prescriptions after "someone in the physician's office told him that the prescription was 'okay' because Horner 'needed to be sedated throughout the day.'"<sup>17</sup> Six days later, on September 27, 1994, Mr. Horner was found dead.<sup>18</sup> An autopsy indicated that his death was caused by the "adverse effects of multiple medications (drugs), especially placidyl . . . , which was near the toxic range."<sup>19</sup>

Mr. Horner's children and mother brought an action for wrongful death against Anthony Spalitto, the pharmacy owner, alleging that Peter Spalitto negligently filled Mr. Horner's prescriptions.<sup>20</sup> In essence, the family argued that Peter Spalitto was negligent in filling Horner's prescription because he (1) "knew or should have known that . . . the dosage . . . would expose [Horner] to unreasonable risk of great bodily harm or death," (2) gave instructions to take the prescribed medication every eight hours when "such dosage far exceeds that recommended," and (3) "fail[ed] to provide [Horner] any warning, either written

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10. *Id.* at 520. The pharmacist he spoke to was Peter Spalitto, the owner's son. *Id.*

11. *Id.* at 521.

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.* at 520. The Horner family settled with the prescribing physician prior to the present litigation. Telephone Interview with John R. Campbell, Jr., Attorney for Plaintiffs, Loughlin, Johnson, & Campbell (July 14, 2000).

or verbal, of the potential side-effects or adverse reactions to said drug or the dangers created by taking it in conjunction with other drugs or pharmaceuticals.”<sup>21</sup>

On December 19, 1997, Spalitto filed a motion for summary judgment, alleging that the pharmacy had breached no duty to Horner because (1) Peter Spalitto had correctly filled the prescription as it was written, and (2) the written prescription had no “apparent irregularities on its face.”<sup>22</sup> That motion was granted on July 22, 1998; the trial court found that Spalitto had breached no duty to Horner, based on the holding of *Kampe v. Howard Stark Professional Pharmacy, Inc.*<sup>23</sup> *Kampe* held that pharmacists fulfill their duties “[b]y properly filling legal prescriptions that contain[] no apparent discrepancies on their face.”<sup>24</sup> According to the trial court, Spalitto had breached no duty because the family had not alleged that Spalitto had made a mistake in filling the prescription.<sup>25</sup>

The Missouri Court of Appeals for the Western District of Missouri disagreed with the trial court and found that Anthony Spalitto may have had a duty to do more than accurately fill Horner’s prescription.<sup>26</sup> The court noted that Missouri’s statutory definition of the practice of pharmacy includes consultation,<sup>27</sup> that Missouri expressly includes pharmacists as “health care workers,”<sup>28</sup> that the Omnibus Budget Reconciliation Act of 1990 (“OBRA”)

21. *Horner v. Spalitto*, 1 S.W.3d 519, 521 (Mo. Ct. App. 1999). The Horner family also alleged that Spalitto was negligent by not investigating whether Horner had a drug abuse problem, by not questioning why Horner had two prescriptions filled on the same day, and by “failing to ascertain what other prescriptions or other drugs [Horner] was taking at the time.” *Id.*

22. *Id.*

23. *Id.* at 522.

24. *Kampe v. Howard Stark Prof’l Pharmacy, Inc.*, 841 S.W.2d 223, 227 (Mo. Ct. App. 1992).

25. *Horner*, 1 S.W.3d at 522.

26. *Id.* The case was set for trial in September 2000. Telephone Interview with John R. Campbell, Jr., *supra* note 20.

27. *Horner v. Spalitto*, 1 S.W.3d 519, 522 (Mo. Ct. App. 1999). The practice of pharmacy is statutorily defined as:

The interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs and devices pursuant to prescription orders; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy.

MO. REV. STAT. § 338.010.1 (1994).

28. *Horner*, 1 S.W.3d at 522. Section 538.205(4) of the Missouri Revised Statutes

required Missouri and other states to establish standards for “pharmacist counseling of pharmacy customers,”<sup>29</sup> and that pharmacists have the education and training to ascertain whether a prescription may be harmful and are in the best position to take corrective action.<sup>30</sup> The *Horner* court therefore overruled *Kampe*, finding that in particular cases pharmacists’ duty to “exercise the care and prudence that a reasonably careful and prudent pharmacist would exercise in the same or similar circumstances,” may require the pharmacist to do more than merely fill an order to help protect patrons from reasonably foreseeable risks.<sup>31</sup>

### III. LEGAL BACKGROUND

#### *A. Common Law Approaches to Pharmacists’ Duty: The Traditional and Modern Approach*

Cases addressing pharmacists’ duty of care often involve a “duty to warn” patients of the dangers of the prescribed medication.<sup>32</sup> Two approaches toward

defines health care providers as: “Any physician, hospital, ambulatory surgical center, long-term care facility, dentist, registered or licensed practical nurse, optometrist, podiatrist, pharmacist, chiropractor, professional physical therapist, psychologist, physician-in-training, and any other person or entity that provides health care services under the authority of a license or certificate.” MO. REV. STAT. § 538.205(4) (1994).

29. *Horner*, 1 S.W.3d at 523. To comply with OBRA, Missouri adopted Title 4, Section 220-2.190 of the Missouri Code of Regulations, which states:

(1) Upon a receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist’s immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained. . . . The elements of counseling shall include matters which the pharmacist deems significant in the exercise of his/her professional judgment and is consistent with applicable state laws.

MO. CODE REGS. ANN. tit. 4, § 220-2.190 (1993).

30. *Horner*, 1 S.W.3d at 523.

31. *Id.* at 522.

32. See, e.g., *Ingram v. Hook’s Drugs, Inc.*, 476 N.E.2d 881 (Ind. Ct. App. 1985) (discussing duty to warn of side effects of prescription medication); *Nichols v. Cent. Merch., Inc.*, 817 P.2d 1131 (Kan. Ct. App. 1991) (discussing duty to warn mother of child of dangers of taking prescription medication while pregnant); *Gassen v. E. Jefferson Gen. Hosp.*, 628 So. 2d 256 (La. Ct. App. 1993) (discussing duty to write out prescription properly); *Kinney v. Hutchinson*, 449 So. 2d 696 (La. Ct. App. 1984) (discussing duty to warn patient of the adverse effect of taking prescription medication with alcohol); *Carafelle v. Brockton Oaks CVS, Inc.*, No. 94-0414A, 1996 Mass. Super.

this duty have evolved in the law: the traditional approach and the modern approach. The traditional approach imposes a duty only "to accurately fill valid prescriptions as directed by the treating physician."<sup>33</sup> Under the traditional view, a pharmacist is a "technician," whose duty is simply to accurately dispense the drugs themselves.<sup>34</sup> The modern approach, however, more fully recognizes pharmacists' knowledge and training. As one court recently observed, "some courts have moved away from strict adherence to [the] traditional view recognizing the expanded role pharmacists take in healthcare. . . . 'pharmacists play a vital role in determining the success or failure of drugs.'"<sup>35</sup> This recognition of the role that pharmacists play in providing health care for patients carries with it increased responsibilities to their patrons.

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LEXIS 421 (Mass. Dist. Ct. Apr. 1996) (discussing duty to warn the patient and physician that the patient is refilling a prescription excessively); *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381 (Mich. Ct. App. 1987) (discussing duty to warn of side effects of medication); *Hand v. Krakowski*, 89 A.D.2d 650 (N.Y. App. Div. 1982) (discussing a duty to warn a known alcoholic of danger of taking prescription drugs with alcohol); *Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987) (discussing duty to warn mother of child born with congenital abnormalities of risks of taking medication while pregnant); *Riff v. Morgan Pharmacy*, 508 A.2d 1247 (Pa. Super. Ct. 1986) (discussing duty to warn of maximum allowable dosage); *Pittman v. Upjohn Co.*, 890 S.W.2d 425 (Tenn. 1994) (discussing duty to warn of hazards of medication); *Dooley v. Everett*, 805 S.W.2d 380 (Tenn. Ct. App. 1990) (discussing duty to warn of drug interaction); *Silves v. King*, 970 P.2d 790 (Wash. Ct. App. 1999) (discussing duty to warn patient of possible drug interactions).

33. Lauren Fleischer, *From Pill-Counting to Patient Care: Pharmacists' Standard of Care in Negligence Law*, 68 *FORDHAM L. REV.* 165, 168 (1999).

34. *Id.* "In fact, the 1952 Code of Ethics for the industry expressly discouraged pharmacists from advising customers about drugs and drug therapy, even when a customer sought such information." *Id.* Thus, the traditional view requires clerical accuracy but little else. *Id.* That view was expressed by a statement attributed (albeit wrongfully) to Former Chief Justice Warren Burger, who purportedly stated that a pharmacist "no more renders a true professional service than does a clerk who sells law books." Michael J. Holleran, *The Pharmaceutical Access and Prudent Purchasing Act of 1990: Federal Law Shifts the Duty to Warn from the Physician to the Pharmacist*, 26 *AKRON L. REV.* 77, 83 n.40 (1992) (noting also the inaccuracy of the statement).

35. *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 890 (W.D. Ark. 1999) (quoting Fleischer, *supra* note 33, at 169).

## 1. The Traditional Approach

The traditional approach is currently the majority view.<sup>36</sup> Most courts following the traditional view reason that requiring pharmacists to adhere to a higher standard would harm the physician-patient relationship and would require a pharmacist, who is arguably inferior in training and education, to make decisions that are best left to board licensed physicians. For example, in *Walker v. Jack Eckerd Corp.*,<sup>37</sup> the Georgia Court of Appeals held that a pharmacist had no duty to warn a patient of a drug's dangerous propensities.<sup>38</sup> The court cited various public policies that supported its view, including:

[T]he need for preserving, without interference of third parties, a trusted physician-patient relationship, the fact that patients have different reactions to and tolerances for drugs coupled with the fact that the severity of a patient's condition may warrant a different level of risk acceptance, which factors are best monitored and evaluated by doctors, and the public policy of this state for reducing frivolous malpractice actions against professionals . . . .<sup>39</sup>

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36. See, e.g., *Pysz v. Henry's Drug Store*, 457 So. 2d 561, 562 (Fla. Dist. Ct. App. 1984) (noting that in Florida, a pharmacist is not liable if (1) the drug is properly compounded, (2) "due and proper care" was used when filling the order, (3) "proper methods were used," and (4) the "drug has not been infected with some . . . foreign substance"); *Walker v. Jack Eckerd Corp.*, 434 S.E.2d 63 (Ga. Ct. App. 1993); *Gassen v. E. Jefferson Gen. Hosp.*, 628 So. 2d 256, 258 (La. Ct. App. 1993) (holding that "a pharmacist does not have a duty to warn a patient of adverse reactions" except in certain circumstances); *Stebbins v. Concord Wrigley Drugs, Inc.*, 416 N.W.2d 381, 387 (Mich. Ct. App. 1987) (finding that a pharmacist "may be held liable for negligently dispensing a drug other than that prescribed. . . . [a] pharmacist is generally not held liable for damages resulting from a correctly filled prescription" (citation omitted)); *New York County Diet Drug Litig. v. Robins*, 262 A.D.2d 132, 132 (N.Y. 1999) (noting that because "there is no allegation that the pharmacy defendants failed to fill the prescriptions precisely as they were directed . . . there is no basis to hold the pharmacists liable"); *Ferguson v. Williams*, 399 S.E.2d 389, 393 (N.C. Ct. App. 1991) ("A druggist simply has the duty to act with due, ordinary care and diligence in compounding and selling drugs."); *Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374, 379 (Pa. Super. Ct. 1987) (finding "no benefit to be derived from the imposition of strict liability upon the pharmacist who properly dispenses a prescription drug upon the prescription of a duly licensed physician"); *Silves v. King*, 970 P.2d 790, 794 (Wash. Ct. App. 1999) (noting that a pharmacist has a duty to accurately fill a prescription, but has no duty to warn the patient).

37. 434 S.E.2d 63 (Ga. Ct. App. 1993).

38. *Id.* at 67.

39. *Id.* (citations omitted).



Therefore, the court found that while the pharmacist owes the customer "prudence, thoughtfulness, and diligence," the pharmacist has no duty to either warn or notify the customer or physician because "[p]lacing these duties to warn on the pharmacist would only serve to compel the pharmacist to second guess every prescription a doctor orders in an attempt to escape liability."<sup>40</sup>

The Washington Supreme Court expressed the same concern in *McKee v. American Home Products, Corp.*<sup>41</sup> In *McKee*, the plaintiff had been prescribed Plegine<sup>42</sup> for approximately ten years; those prescriptions were filled accurately by the defendant pharmacists.<sup>43</sup> McKee alleged that the pharmacists were negligent by failing to warn her of the dangers of long term usage of the drug.<sup>44</sup> The *McKee* court disagreed, finding that a pharmacist has no duty to warn a patient of "potential hazards associated with drug use."<sup>45</sup> Rather, the physician has the duty to "monitor prescription drug usage and a pharmacist will not be found liable for lawfully filling a prescription issued by a licensed physician."<sup>46</sup> Again, as the rationale for its decision, the court emphasized the detrimental effect that applying heightened standards to pharmacists would have on the physician-patient relationship:

To impose a duty to warn on the pharmacist . . . would be to place the pharmacist between the physician who, having prescribed the drug presumably knows the patient's present condition as well as his or her complete medical history, and the patient. Such interference in the patient-physician relationship can only do more harm than good.<sup>47</sup>

Interjecting pharmacists into the physician-patient relationship seemed most troublesome to the *McKee* court because of the disparity in the education of

40. *Id.* at 68. The court also found that:

It is the duty of the prescribing physician to know the character of the drug he is prescribing, to know how much of the drug he can give his patient, to elicit from the patient what other drugs the patient is taking, to properly prescribe various combinations of drugs, to warn the patient of any dangers associated with taking the drug, to monitor the patient's dependence on the drug, and to tell the patient when and how to take the drug.

*Id.*

41. 782 P.2d 1045 (Wash. 1989).

42. Plegine, a potentially addictive amphetamine, was prescribed to McKee as "an appetite suppressant . . . to control an ostensible weight problem." *Id.* at 1046.

43. *Id.* at 1047.

44. *Id.*

45. *Id.* at 1055-56.

46. *Id.* at 1049-50 (noting further that the physician "is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy" (quoting W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 96, at 688 (5th ed. 1984))).

47. *Id.* at 1051.

pharmacists and physicians. The court believed that “pharmacists are not doctors and are not licensed to prescribe medication because they lack the physician’s rigorous training in diagnosis and treatment.”<sup>48</sup> The court seemed to imply that because the pharmacist does not have the same education as the prescribing physician and is not able to prescribe medication, she should not be required to make medical judgments relating to her customers.

In *Fakhouri v. Taylor*,<sup>49</sup> the Illinois Court of Appeals found that a pharmacist has no duty to warn a patient or customer that a prescription calls for an excessive dose.<sup>50</sup> In that case, Frank Fakhouri sued two pharmacists for wrongful death, alleging that the pharmacists were negligent in filling prescriptions for unusually high quantities of Imipramine and by not warning either the patient or the doctor “that the prescriptions were for an excessive and unsafe quantity.”<sup>51</sup> After reviewing Illinois precedent that uniformly held that pharmacists have no duty to warn, the court stated that prescriptions necessarily require a physician to make medical decisions that, according to the court, “only the patient’s physician can provide.”<sup>52</sup> Both the concern that pharmacists lack the education and experience necessary to make medical decisions, and the fear of interjecting the pharmacist “in the middle of the doctor-patient relationship”<sup>53</sup> caused the *Fakhouri* court to decline to require a pharmacist to warn patients that their prescription calls for an excessive dosage.

Until *Horner*, Missouri adhered to the traditional approach. In *Kampe*, the Missouri Court of Appeals for the Western District of Missouri found that “[b]y properly filling legal prescriptions that contained no apparent discrepancies on their face, the pharmacy fulfilled its duty.”<sup>54</sup> In *Kampe*, Howard Stark Professional Pharmacy filled prescriptions for Kampe, but allegedly did not “monitor or evaluate” his use of that medication.<sup>55</sup> The question for the court was whether the pharmacy could be held liable for accurately filling legal prescriptions because of a failure “to monitor a consumer’s use of prescription drugs.”<sup>56</sup> The court cited other jurisdictions that had held that no duty existed,<sup>57</sup>

48. *Id.*

49. 618 N.E.2d 518 (Ill. App. Ct. 1993).

50. *Id.* at 522.

51. *Id.* at 519.

52. *Id.* at 521.

53. *Id.*

54. *Kampe v. Howard Stark Prof'l Pharmacy, Inc.*, 841 S.W.2d 223, 227 (Mo. Ct. App. 1992).

55. *Id.* at 223.

56. *Id.* at 223-24.

57. See *Nichols v. Cent. Merch., Inc.*, 817 P.2d 1131, 1133 (Kan. Ct. App. 1991) (holding that pharmacist had no duty to warn of “potential consequences from the use of the drug prescribed by the doctor”); *Duensing v. Huscher*, 431 S.W.2d 169 (Mo. 1968) (upholding verdict for plaintiff when a pharmacist erred by filling the prescription with the wrong drug); *McKee v. Am. Home Prods., Corp.*, 782 P.2d 1045 (Wash. 1989).

and found that absent a mistake on the part of the pharmacist in filling a legal prescription, no duty would arise.

The *Kampe* court also analyzed Section 338.010.1 of the Missouri Revised Statutes, which defines the practice of pharmacy.<sup>58</sup> While the statute does define the practice of pharmacy to include consultation and evaluation of prescription orders, the court found that the statute did not control the case.<sup>59</sup> Because the statute was revised to include provisions calling for consultation and evaluation in 1990, and *Kampe*'s cause of action accrued on September 29, 1989, applying the statute to the case would require retroactive application, which the court was not willing to do.<sup>60</sup>

The *Kampe* court also categorized Section 338.010 as "definitional" in nature, and noted that it therefore "does not purport to set forth duties."<sup>61</sup> The court supported that view with the language of Section 338.015.2 of the Missouri Revised Statutes, which states that "pharmacists *may* provide pharmaceutical consultation."<sup>62</sup> Emphasizing the Missouri legislature's use of the word "may" rather than "shall," the court found that "by using 'may,' the legislature did not intend to mandate pharmacists to provide consultation and advice to their customers."<sup>63</sup>

The *Kampe* court then addressed the applicable Code of Federal Regulations, stating that the regulations do not address any "duty to advise."<sup>64</sup> The court therefore held that "[b]y properly filling legal prescriptions that contained no apparent discrepancies on their face, the pharmacy fulfilled its duty to [*Kampe*]."<sup>65</sup>

## 2. The Modern Approach

Recently, the traditional belief that a "pharmacy is no more than a warehouse for drugs and that a pharmacist has no more responsibility than a shipping clerk who must dutifully and unquestionably obey the written orders of omniscient physicians" has been rejected, with courts increasingly turning to

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58. See MO. REV. STAT. § 338.010.1 (1994); see also *supra* note 27 and accompanying text.

59. *Kampe v. Howard Stark Prof'l Pharmacy, Inc.*, 841 S.W.2d 223, 226 (Mo. Ct. App. 1992).

60. *Id.* (stating the general rule that statutes will not be applied retrospectively unless there has been "(1) clear manifestation of legislative intent to apply a statute retrospectively, [or the case involves] (2) a statute that is procedural only, not affecting any substantive rights of the parties").

61. *Id.*

62. *Id.* (emphasis added); MO. REV. STAT. § 338.015.2 (1994).

63. *Kampe*, 841 S.W.2d at 226.

64. *Id.*

65. *Id.* at 227.

what may be termed the “modern view” of pharmaceutical duties of care.<sup>66</sup> Courts adopting the modern view show an increased recognition of pharmacists’ place in the health care system, leading to the belief that in performing their professional duties they should be held to the “standard of care, skill, [and] intelligence which ordinarily characterizes the profession.”<sup>67</sup> Therefore, under the modern view a pharmacist is treated by the courts as are other professionals. Courts adhering to this view recognize the pharmacist-patient relationship, pharmacists’ increased training, and the integral role pharmacists play in the current health care system.

The Arizona Supreme Court adopted the modern approach in *Lasley v. Shrake’s Country Club Pharmacy, Inc.*<sup>68</sup> In *Lasley*, the defendant pharmacy provided Lasley with Doriden<sup>69</sup> and codeine<sup>70</sup> over a ten year period pursuant to a valid prescription.<sup>71</sup> Lasley became addicted to the medications, requiring hospitalization and psychiatric care for his addiction.<sup>72</sup> Lasley argued that Shrake’s had a duty to warn him of the drugs’ dangers,<sup>73</sup> but Shrake’s contended that it owed no duty to Lasley.<sup>74</sup> The *Lasley* court disagreed with Shrake’s, holding that a pharmacist has a duty to act as a prudent and reasonable

66. *Riff v. Morgan Pharmacy*, 508 A.2d 1247, 1251 (Pa. Super. Ct. 1986); *see also Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 890 (W.D. Ark. 1999) (“More recently, some courts have moved away from strict adherence to [the] traditional view recognizing the expanded role pharmacists take in healthcare. It has been recognized that ‘pharmacists play a vital role in determining the success or failure of drugs.’” (quoting *Fleischer*, *supra* note 33, at 169)).

67. *See Dooley v. Everett*, 805 S.W.2d 380, 385 (Tenn. Ct. App. 1990) (“The pharmacist is a professional who has a duty to his customer to exercise the standard of care required by the pharmacy profession in the same or similar communities as the community in which he practices his profession.”); *see also Riff*, 508 A.2d at 1251 (“Public policy requires that pharmacists who prepare and dispense drugs and medicines for use in the human body must be held responsible for the failure to exercise the degree of care and vigilance commensurate with the harm likely to result from relaxing it.”).

68. 880 P.2d 1129 (Ariz. Ct. App. 1994).

69. “Doriden is a sedative prescribed for short term relief of insomnia.” Ivelisse Cruz, Note, *The Pharmacist and Patient Counseling: Models for Imposing Liability*, 4 J. PHARMACY & LAW 237, 237 (1995) (noting further that DRUG FACTS AND COMPARISONS, an authoritative pharmaceutical manual, suggests that the drug be administered for “three to seven days”).

70. Codeine is “prescribed to relieve pain.” *Id.* “[P]rolonged use of either [Doriden or Codeine] produces physical and psychological dependence.” *Id.* (citing FACTS AND COMPARISONS, INC., DRUG FACTS AND COMPARISONS 271a-271c (1994)).

71. *Lasley*, 880 P.2d at 1131.

72. *Id.*

73. *Id.*

74. *Id.*

pharmacist, which may include warning a patient of a drug's dangerous propensities.<sup>75</sup> Other courts have similar holdings.<sup>76</sup>

Courts that utilize the modern approach view the pharmacist as an important part of effective health care. In *Cafarelle v. Brockton Oaks CVS, Inc.*,<sup>77</sup> the parents of Jennifer Cafarelle, a 13-year-old who died of acute respiratory failure sued the pharmacists who supplied her asthma medication.<sup>78</sup> Jennifer's parents alleged that the pharmacist who refilled her asthma medication "should have refused to refill the prescriptions before the normal time and should have warned Jennifer, her parents, and/or her physician that Jennifer was overusing the prescribed medication and that such overuse was potentially dangerous."<sup>79</sup> The Superior Court of Massachusetts found that CVS "had a duty to exercise that degree of care that an ordinarily prudent pharmacist would have exercised under the same or similar circumstances."<sup>80</sup> In so holding, the court noted the special relation that the pharmacist has to the client, in part because the pharmacist may be in a better position to evaluate the client's current condition.<sup>81</sup> The court also departed from the traditional view's implied assertion that pharmacists simply "get in the way" of the physician-patient relationship. Instead, the court asserted that "pharmacists and physicians can work together to provide the best care available to all patients."<sup>82</sup>

Other courts have found that the pharmacist has a special relation to the customer, almost akin to that of the physician-patient relationship. In *Hooks SuperX, Inc. v. McLaughlin*,<sup>83</sup> the Indiana Supreme Court broke from precedent to find that in certain cases the pharmacist has a duty to refuse to refill a prescription.<sup>84</sup> The court reasoned that holding the pharmacist to that higher standard is "simply a practical recognition of the relationship between pharmacist

75. *Id.* at 1132.

76. See, e.g., *Heredia v. Johnson*, 827 F. Supp. 1522 (D. Nev. 1993) (finding a duty to take corrective action when prescription contains a fatal dose of medication); *Hooks SuperX, Inc. v. McLaughlin*, 632 N.E.2d 365 (Ind. Ct. App. 1994) (vacated on other grounds) (finding that pharmacist has a limited duty); *People's Serv. Drug Stores v. Somerville*, 158 A. 12 (Md. 1932); *Nevada State Bd. Pharmacy v. Garrigus*, 496 P.2d 748 (Nev. 1972) (stating that a pharmacist may have duty not to fill unusual prescriptions); *Hand v. Krakowski*, 89 A.D.2d 650 (N.Y. App. Div. 1982) (finding a duty to warn a customer known to be an alcoholic of the danger involved in taking medication with alcohol).

77. No. 94-0414A, 1996 Mass. Super. LEXIS 421 (Mass. Dist. Ct. Apr. 1996).

78. *Id.* at \*1.

79. *Id.*

80. *Id.* at \*29-30.

81. *Id.* at \*27.

82. *Id.*

83. 642 N.E.2d 514 (Ind. 1994).

84. *Id.* at 519.

and customer,"<sup>85</sup> and the fear that imposing higher standards on pharmacists will create an adversarial relationship between the pharmacist and the physician is unfounded.<sup>86</sup> Rather, the physicians "remain ultimately responsible for properly prescribing medication, and recognition of a duty on the part of pharmacists will not replace the physician's obligation to evaluate a patient's needs."<sup>87</sup>

Some courts utilize what appears to be a "hybrid" analysis, only requiring heightened care in certain circumstances.<sup>88</sup> For example, in *Hendricks v. Charity Hospital of New Orleans*,<sup>89</sup> the Louisiana Court of Appeals implicitly found that when a pharmacist is confronted with a prescription giving an excessive dosage, the pharmacist has the duty to warn the patient of the dangers of taking the prescription as ordered.<sup>90</sup> In that case, a physician unintentionally prescribed 500 mg. of Dilantin every eight hours, instead of 500 mg. daily.<sup>91</sup> Hendricks attempted to fill that prescription, but the pharmacist, who was suspicious of the high dosage, sent the customer back to his doctor.<sup>92</sup> Unfortunately, when the patient asked the physician to review the prescription, the physician again misread the dosage.<sup>93</sup> When Hendricks returned with the same prescription, the

85. *Id.*

86. *Id.*; see also *Cafarelle v. Brockton Oaks CVS, Inc.*, No. 94-0414A, 1996 Mass. Super. LEXIS 421, at \*27 (Mass. Dist. Ct. Apr. 1996) ("Doctors still have the ultimate responsibility to evaluate the patient's needs and prescribe the appropriate medication. However, a pharmacist may be in the best position to know when a patient is refilling prescriptions at too fast a rate, and to alert the patient and the physician of the situation.").

87. *Hooks SuperX*, 642 N.E.2d at 519.

88. See, e.g., *Heredia v. Johnson*, 827 F. Supp. 1522, 1525 (D. Nev. 1993) ("It is not for the pharmacist to second guess a licensed physician unless in such circumstances that would be obviously fatal. . . . [I]t is clear that the attending pharmacist owes some duty to persons for whom he or she is filling prescriptions. . . . At a minimum, a pharmacist must be held to a duty to fill prescriptions as prescribed."); *Hooks SuperX*, 642 N.E.2d at 518 (holding that pharmacists may be held liable for filling prescriptions faster than normal, depending upon the facts of the case).

89. 519 So. 2d 163 (La. Ct. App. 1987).

90. *Id.* But see *Gassen v. E. Jefferson Gen. Hosp.*, 628 So. 2d 256 (La. Ct. App. 1993). In *Gassen*, the court noted that "[u]nder both common law and under Louisiana jurisprudence a pharmacist does not have a duty to warn a patient of adverse reactions." *Id.* at 258. In *Gassen*, a pharmacist incorrectly copied the administration instructions on the prescription, indicating that the medication should be given intravenously instead of intramuscularly. *Id.* at 256. The court found that pharmacists have "limited dut[ies] to inquire or verify from the prescribing physician clear errors or mistakes in the prescription." *Id.* at 259. The pharmacist did not, however, have a duty "to question a judgment made by the physician as to the propriety of a prescription or to warn customers of the hazardous side effects associated with a drug." *Id.* (citing *McKee v. Am. Home Prods., Corp.*, 782 P.2d 1045 (Wash. 1989)).

91. *Hendricks*, 519 So. 2d at 164.

92. *Id.* at 164-65.

93. *Id.*

pharmacist called the physician's office, left a message for the physician, then filled the prescription and included a note: "Patient should consult Physician about dosage."<sup>94</sup> The court agreed with the trial court that the pharmacist "could be expected to do no more" and dismissed the charges against the pharmacist.<sup>95</sup>

## B. Statutory Definitions and Standards

### 1. Federal Statutes

In 1990, Congress enacted the Omnibus Budget Reconciliation Act ("OBRA").<sup>96</sup> OBRA required states to adopt more stringent standards for pharmacists by January 1, 1993 in order to receive Medicare matching funds from the federal government.<sup>97</sup> Although only required to pass legislation expanding pharmacy practice standards for Medicare patients, most states applied those standards to all pharmacy customers.<sup>98</sup> Specifically, OBRA required states to establish (1) a drug review board,<sup>99</sup> (2) both retrospective and prospective drug review,<sup>100</sup> (3) requirements that pharmacists counsel patients about prescription drug use,<sup>101</sup> and (4) requirements that pharmacists request information from the patient.<sup>102</sup>

The new "drug use review" standards were designed to "assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results."<sup>103</sup> Any drug use review proposed by

94. *Id.* at 165.

95. *Id.*

96. The Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388-151 (codified as amended at 42 U.S.C. § 1396r-8(g) (1994)). OBRA required certain standards from pharmacists because it sought to reduce costs associated with drug therapy problems. *See, e.g.,* Brenda Jones Quick, *The Cost of the Omnibus Budget Reconciliation Act of 1990*, 2 J. PHARMACY & L. 145, 148 (1994); *see also* Kenneth R. Baker, *The OBRA 90 Mandate and Its Developing Impact on the Pharmacist's Standard of Care*, 44 DRAKE L. REV. 503, 503 (1996) (stating that congressional efforts at decreasing costs of Medicaid led to the adoption of expanded standards for pharmacists).

97. *See* 42 U.S.C. § 1396r-8(g)(2) (1994).

98. *See* David B. Brushwood, *The Pharmacist's Duty Under OBRA-90 Standards*, 18 J. LEGAL MED. 475, 485 (1997); *see also* John C. West & David E. Smith, *A Prescription for Liability: The Pharmacy Mandate of the Omnibus Budget Reconciliation Act of 1990 and Its Impact Upon Pharmacists' Common Law Duties*, 2 J. PHARMACY & L. 127, 129 (1993) (stating that "at least forty-one states now require [drug use review] programs for all patients presenting prescriptions to pharmacists").

99. *See* 42 U.S.C. § 1396r-8(g)(3)(A) (1994).

100. *See* 42 U.S.C. § 1396r-8(g)(2)(A)-(B) (1994).

101. *See* 42 U.S.C. § 1396r-8(g)(2)(A)(ii)(I) (1994).

102. *See* 42 U.S.C. § 1396r-8(g)(2)(A)(ii)(II) (1994).

103. 42 U.S.C. § 1396r-8(g)(2)(A)(ii)(II) (1994). Congress specifically required, through OBRA, that the drug use program "educate physicians and pharmacists . . .

<https://scholarship.law.missouri.edu/mlr/vol65/iss4/9>

a state is intended to "educate physicians and pharmacists" to reduce "potential and actual severe adverse reactions to drugs."<sup>104</sup> The drug use review program involves prospective review,<sup>105</sup> retrospective review,<sup>106</sup> and educational programs.<sup>107</sup>

Prospective review requires the pharmacist to screen the prescriptions she encounters, and also to offer to counsel customers. The screening function requires pharmacists to look for "potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of treatment, drug-allergy interactions and clinical abuse/misuse."<sup>108</sup> Implicitly, if the pharmacist finds a mistake or error in the prescription, the very least she would seem to be required to do is to draw that mistake to the customer's attention.

OBRA also requires pharmacists to offer to counsel patients. It requires the pharmacists to offer to discuss topics relevant to the customer's prescription, including "[t]he name and description of the medication," "[t]he route, dosage form, dosage, route of administration, and duration," "[s]pecial directions and precautions," and "[c]ommon severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur."<sup>109</sup>

Also included within the "prospective review" category is the requirement that pharmacists try to "obtain, record, and maintain" the patient's personal information.<sup>110</sup> Thus, the pharmacist must make a reasonable attempt at obtaining the name, address, phone number, and medical history of the patient.<sup>111</sup>

Retrospective review merely attempts to provide a continual examination of claims data to increase the efficiency of the health care system and increase the overall quality of care given.<sup>112</sup> The educational program requires states to "educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices."<sup>113</sup>

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[about] potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, . . . incorrect drug dosage or duration of drug treatment." 42 U.S.C. § 1396r-8(g)(2)(A)(ii)(II) (1994).

104. 42 U.S.C. § 1396r-8(g)(1)(A) (1994).

105. See 42 U.S.C. § 1396r-8(g)(2)(A) (1994).

106. See 42 U.S.C. § 1396r-8(g)(2)(B) (1994).

107. See 42 U.S.C. § 1396r-8(g)(2)(D) (1994).

108. 42 U.S.C. § 1396r-8(g)(2)(A) (1994).

109. 42 U.S.C. § 1396r-8(g)(2)(A) (1994).

110. 42 U.S.C. § 1396r-8(g)(2)(A)(II) (1994).

111. See 42 U.S.C. § 1396r-8(g)(2)(A)(II) (1994).

112. See 42 U.S.C. § 1396r-8(g)(2)(B) (1994).

113. 42 U.S.C. § 1396r-8(g)(2)(D) (1994).



## 2. State Statutes

State legislatures appear to be adopting the modern view of pharmacists' duty of care. Statutorily, many states have begun to define "the practice of pharmacy" to include areas that were previously reserved for physicians, such as consultation.<sup>114</sup> In 1988, for example, thirty of the forty-one states analyzed included consultation of patients in the definition of the practice of pharmacy, whereas in 1998 forty-one out of forty-seven states included the term.<sup>115</sup> The increase in broad definitions of the practice of pharmacy reflects "the evolution of pharmacy practice, as the pharmacist becomes more responsible for patient outcomes."<sup>116</sup>

In Missouri, the practice of pharmacy is defined as:

[T]he interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs and devices pursuant to prescription orders; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; *consultation with patients and other health care practitioners about the safe and effective use of drugs and devices.*<sup>117</sup>

Furthermore, "[a]ll pharmacists *may* provide pharmaceutical consultation and advice to persons concerning the safe and therapeutic use of their prescription drugs."<sup>118</sup> The permissive language of the statute (i.e., the use of the word "may")

114. Indeed, counseling has become so commonplace in the pharmaceutical practice that "the question for pharmacists is no longer 'Should I counsel?' but 'What should I say when I counsel?'" Justina A. Molzon, *The FDA's Perspective on the Future of Pharmacy*, 44 *DRAKE L. REV.* 463, 464 (1996).

115. See Melissa D. Young et al., *Pharmacy Practice Acts: A Decade of Progress*, 33 *THE ANNALS OF PHARMACOTHERAPY* 920, 923 (1999). Furthermore, "[p]atient assessment, consisting of authorization to order laboratory tests for therapeutic drug monitoring," was included in six out of forty-seven states in 1998; it was included in one state's definition in 1988. *Id.* Some states' statutory definitions are indeed very broad. For example, in Iowa and California, the "practice of pharmacy" is defined as a "dynamic patient-oriented health service profession that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use and related drug therapy." *Id.* at 924.

116. *Id.*

117. *MO. REV. STAT. § 338.010* (1994) (emphasis added).

118. *MO. REV. STAT. § 338.015* (1994) (emphasis added). The use of the word "may" in Missouri's definition may change. House Bill 1743, introduced in the 2000 Missouri Legislative Session, would change the definition of pharmacy by increasing the scope of "consultation" and by allowing pharmacists to "engage in initiating or modifying drug therapy . . . in accordance with . . . written guidelines or protocols previously established for the pharmacist's practice by the referring practitioner." H.B.

rather than "shall") may be somewhat misleading. In 1993, the Missouri State Board of Pharmacy promulgated Title 4, Section 220-2.190 of the Missouri Code of State Regulations to comply with OBRA. In that regulation, Missouri pharmacists are required to "personally offer to discuss matters which will enhance or optimize drug therapy with each patient."<sup>119</sup> Therefore, in keeping with federal legislation, Missouri pharmacists must at least offer to counsel their patients. Importantly, those regulations were promulgated in 1993, one year after the Missouri Court of Appeals decided *Kampe*.<sup>120</sup>

### *C. Pharmaceutical Science, Education, and Professional Standards*

Scholars have also noted that pharmacists often have a better opportunity to reduce medication-based risks. First, often patients have only one pharmacist but multiple doctors.<sup>121</sup> Therefore, a pharmacist may have more of a "relationship" with the patient than the doctor, and may have more complete records of allergies.<sup>122</sup> Furthermore, when a patient refills medication, often no return trip to the doctor's office is necessary, and therefore the pharmacist is the

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1743, 90th Gen. Assem., 2d Sess. (Mo. 2000), available at <http://www.house.state.mo.us/bills00/biltx00/intro00/HB1743I.htm>.

Consultation would be redefined to include:

[T]he advising of therapeutic values, hazards, adverse reactions, drug interactions or drug use; the monitoring of drug use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established for the pharmacist's practice by a practitioner authorized to prescribe drugs.

H.B. 1743.

Therefore, under the proposed statute, and others like it, pharmacists would have limited prescribing authority. See Deborah E. Boatwright, *Legal Aspects of Expanded Prescribing Authority for Pharmacists*, 55 AM. J. HEALTH-SYS. PHARMACISTS 585, 587 (1998) ("Most states that have embraced prescribing authority for pharmacists are favoring a model in which the prescribing pharmacist is a dependent prescriber.").

The bill would make such consultation mandatory, stating that "all pharmacists shall offer pharmaceutical consultation," thereby clearing up any residual confusion between the language of Title 4, Section 220-2.190 of the Missouri Code of State Regulations and the *Kampe* precedent. H.B. 1743 (emphasis added). Importantly, the statute has not yet been adopted.

119. MO. CODE REGS. ANN. tit. 4, § 220-2.190 (1993).

120. See *Kampe v. Howard Stark Prof'l Pharmacy, Inc.*, 841 S.W.2d 223 (Mo. Ct. App. 1992), *abrogated by* *Horner v. Spalitto*, 1 S.W.3d 519 (Mo. Ct. App. 1999); MO. CODE REGS. ANN. tit. 4, § 220-2.190 (1993).

121. See David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 DRAKE L. REV. 439, 441-42 (1996).

122. For a discussion of OBRA, which mandates that states adopt rules requiring pharmacists to make reasonable attempts at obtaining patient information, see *supra* Part III.B.1.

only professional the patient sees between refills.<sup>123</sup> Pharmacists are also accessible because of their often convenient office location, by having an "open door policy," and by being open during non-working hours.<sup>124</sup> Lastly, pharmacists simply have more responsibility in today's health care market. As David Brushwood notes, "[r]esponsibility arises because one possesses the ability to respond when confronted with a preventable problem. Because pharmacists' abilities have increased, expanding pharmacists' responsibility and liability is justified as an application of the principle of capacity responsibility."<sup>125</sup>

The evolution of the health care system has also meant that pharmacists do more than fill prescriptions. With the advent of Health Maintenance Organizations ("HMOs"), pharmacists sit on "committees that decide which drugs most effectively and efficiently treat ailments, and create 'formulary' lists from which doctors can prescribe drugs for their patients."<sup>126</sup> Pharmacists have also become more involved with both the medical profession and with patients in drug selection and patient counseling.<sup>127</sup> Various reasons have been cited for increasing the use of pharmacists, including a "recognition that problems resulting from drug therapy are significant in frequency, severity, and cost,"<sup>128</sup> and an implicit recognition that the use of pharmacists alleviates those problems.

Not only has the use of pharmacists increased, but their training and abilities in both science and communication have evolved in recent years. While some courts have cited the education gap between doctors and pharmacists as a reason for declining to expand pharmacists' duties,<sup>129</sup> pharmaceutical education "has evolved over the past several decades from an emphasis on the drug product to an emphasis on drug therapy."<sup>130</sup> In fact, pharmacy students enjoy a very "patient-oriented" curriculum, taking communication courses that are designed to teach them how to convey drug information to both customers and health care providers, "clinical rotations where they are encouraged to make recommendations to the prescriber on drug therapy," and having the opportunity to enter the especially patient-oriented Doctor of Pharmacy programs.<sup>131</sup> Their

123. See Brushwood, *supra* note 121, at 442.

124. Brushwood, *supra* note 121, at 442.

125. Brushwood, *supra* note 121, at 443.

126. Fleischer, *supra* note 33, at 169.

127. See David S. Walker & Stephen G. Hoag, *Symposium on the Evolving Pharmacy Jurisprudence: Changing the Law For a Changing Profession*, 44 DRAKE L. REV. i, at i (1996).

128. *Id.*

129. See *McKee v. Am. Home Prods., Corp.*, 782 P.2d 1045, 1050-51 (Wash. 1989).

130. Brushwood, *supra* note 121, at 441.

131. Gary G. Cacciatore, *Computers, OBRA 90 and the Pharmacist's Duty to Warn*, 5 J. PHARMACY & L. 103, 104 (1996). Such programs may be misleading. As stated by Paul Grussing, the Associate Professor and Acting Head of the Department of Pharmacy Administration at the University of Illinois, "[t]he behaviors at issue in duty-

<https://scholarship.law.missouri.edu/mlr/vol65/iss4/9>

knowledge must be maintained; according to the Code of Ethics for Pharmacists, "[a] pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances."<sup>132</sup>

In Missouri, pharmacists must "be a graduate of a school or college of pharmacy," must "furnish satisfactory evidence of . . . good moral character," and "have had one year practical experience under the supervision of a licensed pharmacist within a licensed pharmacy."<sup>133</sup> Missouri pharmacists must also continue their education; according to Section 338.060(3) of the Missouri Revised Statutes, pharmacists must complete fifteen hours or more of "board-approved continuing education courses" before re-certification.<sup>134</sup>

Pharmacists themselves have embraced the client-centered approach and the attendant increase in their professional responsibilities.<sup>135</sup> In the Code of Ethics for Pharmacists, published by the American Society of Health System Pharmacists ("ASHP"), Principle II demonstrates the use of client-centeredness by requiring that "[a] pharmacist places concern for the well-being of the patient

to-warn cases are basic, fundamental, and deliverable by educated and licensed pharmacists whether they hold a B.S. or Pharm.D. degree." Paul G. Grussing, *A Comparison of Empirical Studies of Pharmacy Practice with Judicial Descriptions*, 44 *DRAKE L. REV.* 483, 484, 486 (1996) (noting further that the need to warn patients of risks related to drug therapy is "written permanently in the students' professional minds and hearts. Fifth year students are, typically, both confused and angered after studying decisions holding [that the] responsibility for warning patients of hazards associated with prescription drug use is limited to the physician-patient relationship . . .").

132. Code of Ethics for Pharmacists, Principle V in American Soc'y of Health-Sys. Pharmacists, *ASHP Statement on Pharmacist Decision-Making on Assisted Suicide*, 56 *AM. J. HEALTH-SYS. PHARMACISTS* 1661, 1663 (1999).

133. *MO. REV. STAT.* § 338.030 (1994).

134. *MO. REV. STAT.* § 338.030 (1994). Board approved education includes that knowledge gained from "institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, professional meetings, self-study courses and any other methods which may be approved by the board, but in any case, the studies must be pharmacy-related." *MO. CODE REGS. ANN.* tit. 4, § 220-2.100 (1998).

135. For pharmacists, at least, the shift from "order fillers" to being responsible and important members of the health care profession has been evolving over the past thirty years. In 1967, D.C. Brodie introduced a concept of pharmaceutical care that embraced "responsibility for all aspects of drug use, ranging from procurement and storage to drug utilization." Walker & Hoag, *supra* note 127, at i. The concept took off, and is "[n]ow widely accepted as the mission of pharmacy practice . . . imply[ing] that pharmacists have both the professional capability and the responsibility to provide health care, not just fill prescriptions and dispense medications." Walker & Hoag, *supra* note 127, at i; see also Grussing, *supra* note 131, at 484 (noting that students of pharmaceutical science often are "confused and angered after studying decisions holding [that the] responsibility for warning patients of hazards associated with prescription drug use is limited to the physician-patient relationship").

at the center of professional practice."<sup>136</sup> Pharmacists are also encouraged to take part in their new role as health care providers; the ASHP recently stated in its *Statement on the Pharmacist's Role in Primary Care* "that pharmacists have a role in meeting the primary care needs of patients through fulfilling their responsibilities in pharmaceutical care."<sup>137</sup> Therefore, pharmacists are urged "to assume leadership, responsibility, and accountability for the quality, effectiveness, and efficiency of the entire medication-use process (including prescribing, dispensing, administration, monitoring, and education) across the continuum of care."<sup>138</sup>

The changing nature of pharmaceutical care from product-oriented to client-centered has caused some pharmacists to question the legal standards applied to their profession. Paul Grussing, Associate Professor and Acting Head of the Department of Pharmacy Administration at the University of Illinois, concluded that "[d]uty-to-warn cases which contradict professional standards and legislative intent . . . create economic incentives to deny society the benefits of its investment in the profession of pharmacy. Pharmacy practice has changed. Let social consciousness allow society to benefit."<sup>139</sup>

Finally, it is clear that the general public expects pharmacists to be part of the overall health care team. Scholars have noted that those who are injured when a pharmacist, a member of the "Most Honorable Profession," has not warned them of adverse side effects of drug therapy "believe that pharmacists should play an important role in the healthcare safety net."<sup>140</sup> In short, some believe that because "[t]he public holds pharmacists in very high esteem, it expects them to help safeguard and advance public health. . . . It is clear that patients expect more from their physicians than simply writing prescriptions. It is equally clear that patients expect their pharmacists to do more than fill prescriptions."<sup>141</sup>

136. Code of Ethics for Pharmacists, *supra* note 132, at 1663. Certainly, this is a far cry from the traditional view of pharmacists as "order fillers."

137. American Soc'y of Health-Sys. Pharmacists, *ASHP Statement on the Pharmacist's Role in Primary Care*, 56 AM. J. HEALTH-SYS. PHARMACISTS 1665, 1665 (1999). "Pharmaceutical care" is a relatively new concept and is defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life." Walker & Hoag, *supra* note 127, at i (quoting Charles D. Hepler & Linda M. Strand, *Opportunities and Responsibilities in Pharmaceutical Care*, 47 AM. J. HOSP. PHARMACY 533, 539 (1990)) (noting further that the concept "implies that pharmacists have both the professional capability and the responsibility to provide health care, not just fill prescriptions and dispense medications.").

138. American Soc'y of Health-Sys. Pharmacists, *Professional Policies Adopted by the 51st Annual Session of the ASHP House of Delegates*, 56 AM. J. HEALTH-SYS. PHARMACISTS 1658, 1658 (1999).

139. Grussing, *supra* note 131, at 491.

140. Fleischer, *supra* note 33, at 169.

141. Molzon, *supra* note 114, at 463-64.

#### IV. INSTANT DECISION

In *Horner*, the Missouri Court of Appeals for the Western District of Missouri revisited the duties of Missouri's pharmacists, ultimately deciding that pharmacists do have a duty to warn their customers in some circumstances. The court held that pharmacists have a duty to "endeavor to minimize the risks of harm . . . which a reasonably careful and prudent pharmacist would foresee."<sup>142</sup> In so doing, the court overruled *Kampe*.

The court first addressed duty generally, defining it as "an obligation imposed by law to conform to a standard of conduct toward another to protect others against unreasonable, foreseeable risks."<sup>143</sup> Therefore, the court stated, Spalitto was under a duty to act as a reasonable pharmacist under the circumstances.<sup>144</sup>

The court next addressed the *Kampe* standard, stating that *Kampe* was incorrect in its holding that pharmacists will never have a duty to do more than accurately fill prescriptions.<sup>145</sup> The court qualified its holding by finding that in some cases a pharmacist may merely have the duty to fill a prescription properly, while in others that duty may extend to protecting "patrons from risks which pharmacists can reasonably foresee."<sup>146</sup> The *Horner* court stated, however, that such a determination of what duty is owed should be left to the jury.<sup>147</sup>

The court also addressed the policy considerations inherent in the choice to extend a pharmacists' duty of care. The court stated that *Kampe*'s holding "denigrate[d] the expertise which a pharmacist's education provides concerning drugs and their therapeutic use."<sup>148</sup> Furthermore, according to the *Horner* court, *Kampe* did not fully appreciate the role of the pharmacist in making "the valuable, but highly dangerous, service of drug therapy as safe and reliable as it can be."<sup>149</sup> The court further noted pharmacists' expertise by stating that it believed that pharmacists have (1) the training and skills needed to recognize that a prescription is incorrect, (2) the ability to communicate concerns about that inaccuracy with the prescribing physician, and (3) the contacts with the physician that enable the pharmacist to not only warn the doctor of the medication's possible dangers, but also the ability to verify that the physician intended the dose that had been prescribed.<sup>150</sup>

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142. *Horner v. Spalitto*, 1 S.W.3d 519, 521 (Mo. Ct. App. 1999).

143. *Id.* at 522.

144. *Id.*

145. *Id.*

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

150. *Id.* at 523.

The court also noted the statutes applicable to pharmacists, including the statute that defines the “practice of pharmacy,”<sup>151</sup> OBRA, and the inclusion of pharmacists in the definition of “health care workers.”<sup>152</sup> Furthermore, the court noted that the term “health care services” includes “any services that a health care provider renders to a patient in the ordinary course of the health care provider’s profession.”<sup>153</sup> Based upon this statutory background, the court found that Section 538.225.1 of the Missouri Revised Statutes, “in effect, sets the pharmacist’s duty by mandating that his action or omission be judged by his peers according to what ‘a reasonably prudent and careful health care provider would have [done] under similar circumstances.’”<sup>154</sup>

The court then specifically addressed the concern that its holding would interfere with the physician-patient relationship, finding that it would not adversely affect that relation, but would instead “increase the overall quality of health care.”<sup>155</sup> The court explicitly recognized that “[p]harmacists are trained to recognize proper dose and contraindications of prescriptions, and physicians and patients should welcome their insights to help make the dangers of drug therapy safer.”<sup>156</sup>

Notably, the court stated that it is still the physician’s responsibility “to assess[] what medication is appropriate for a patient’s condition.”<sup>157</sup> However, “the pharmacist may be in the best position to determine how the medication should be taken to maximize the therapeutic benefit to that patient, to communicate that information to the customer or his physician, and to answer any of the customer’s questions regarding consumption of the medication.”<sup>158</sup> Thus, the court found that by “[r]elegating a pharmacist to the role of order filler” the *Kampe* standard had not recognized the expertise of pharmacists as addressed in Missouri and federal statutes.<sup>159</sup>

Finally, the court refused to determine whether Spalitto had fulfilled his duty as a pharmacist. The court did note certain questions pertinent to that decision, however, asking whether Spalitto had “articulated to the prescribing physician that he was prescribing Placydil at a significantly higher dose than the recommended dose for sedation,” as well as whether he had informed the doctor of the adverse effects of combining Placydil and Diazepam.<sup>160</sup> Because no

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151. *Id.* at 522.

152. *Id.* at 523.

153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.* at 524 n.5.

157. *Id.* at 524.

158. *Id.*

159. *Id.*

160. *Id.*

answers to these questions appeared in the record, the court remanded the case for further proceedings.<sup>161</sup>

## V. COMMENT

In *Horner*, the court adopted a standard that allows the jury to determine whether a pharmacist owed a patient a duty to warn, while recognizing that pharmacists are professionals in their own right. In so doing, it overruled *Kampe* and the traditional analysis of pharmaceutical duties, and adopted an approach that is more akin to the "modern" view of pharmaceutical duties.

The modern approach may require more of Missouri's pharmacists, but it also addresses the need to ensure accuracy in the distribution of pharmaceuticals. Errors such as "choice of the wrong drug, dose, route, form, and frequency or time of administration" occur in up to five percent of all prescriptions.<sup>162</sup> Some studies have reported that fifteen to eighteen percent of all discharge prescriptions contain errors, and that thirty-eight percent of discharges receive one or more drug orders containing mistakes.<sup>163</sup> Interestingly, that study noted that pharmacists detect 1.4 to 3.2% of those errors.<sup>164</sup>

Those jurisdictions that hold on to the traditional approach support their adherence to that view with certain assumptions. First, courts often suggest that the pharmacist would be an unwelcome bedfellow in the physician-patient relationship.<sup>165</sup> That is simply not the case. Rather, pharmacists seem to be expected by the health care community to find and fix errors in prescriptions before the patient suffers an adverse drug event. For example, the *Journal of the American Medical Association* ("JAMA") recently published an article advocating pharmacist participation in medical rounds.<sup>166</sup> That study found that the "presence of the pharmacist on rounds was well accepted by physicians," and ninety-nine percent of the pharmacists' suggestions were accepted by the doctors.<sup>167</sup> The study concluded that "participation of a pharmacist on medical rounds can be a powerful means of reducing the risk of" adverse drug events.<sup>168</sup>

The JAMA article illustrates that pharmacists are not unwelcome members of the health care system. Rather, physicians understand that they occasionally err when they write prescriptions,<sup>169</sup> and depend upon pharmacists to find and

161. *Id.*

162. Nightingale, *supra* note 2, at 750.

163. See Lesar, *Medication-Prescribing Errors in a Teaching Hospital*, *supra* note 2, at 1573 (noting also that adverse drug events occur in 6.5% of hospital admissions).

164. See Lesar, *Medication-Prescribing Errors in a Teaching Hospital*, *supra* note 2, at 1573.

165. See *supra* notes 37-53 and accompanying text.

166. See Leape, *supra* note 7, at 267.

167. See Leape, *supra* note 7, at 269.

168. See Leape, *supra* note 7, at 270.

169. See *supra* notes 2-7 and accompanying text. Certainly, physicians do not



correct the most egregious of those errors. Other articles advocate for requiring pharmacists to recalculate dosages before patients are given the first dose,<sup>170</sup> and for more integration of the pharmacists into the health care team in order to use their expertise more efficiently.<sup>171</sup>

With the health care system's acceptance of pharmacists' expertise and ability to detect errors made by physicians, it is valid to question why courts cannot accept the same. Unfortunately "[d]octors, like other mortals, will from time to time err through ignorance or inadvertence";<sup>172</sup> courts should understand that at times each member of the medical community accepts the role as her "brother's keeper."<sup>173</sup>

The Superior Court of Pennsylvania addressed the courts' intervention into the medical community's self-standardization by eloquently stating: "If the consensus of the medical community is that a safety net of overlapping responsibilities is necessary to serve the best interests of patients, it is not for the judiciary to dismantle the safety net and leave patients at the peril of one man's human frailty."<sup>174</sup> Thus, courts like *Riff* understand that pharmacists do have a place in the health care team, and that their expertise and experience is necessary rather than burdensome.<sup>175</sup>

The second assumption made by courts, closely related to the first, is that pharmacists receive less training than physicians and therefore have less

intentionally err when ordering medication. Rather, errors are often caused by factors such as (1) lack of access to drug-related information, (2) lack of access to the patient's information (such as allergies or other medical conditions), (3) illegible handwritten prescriptions, and (4) lost or unavailable prescription sheets. Nightingale, *supra* note 2, at 750. Common errors committed by physicians include: (1) improper calculations of dosage, (2) errors in decimal points, (3) similarly named medications, (4) problems with medication dosage forms, (5) the use of abbreviations, (6) "unusual routes of drug administration," (7) complicated or uncommon dosage regimens, and (8) lack of information regarding the patient's history. Lesar, *Factors Related to Errors in Medication Prescribing*, *supra* note 2, at 312.

170. See Neil Caldwell, *How to Decrease Errors in Dose*, 137 J. OF PEDIATRICS 142, 142 (2000).

171. See, e.g., Lesar, *Factors Related to Errors in Medication Prescribing*, *supra* note 2, at 316.

172. *Riff v. Morgan Pharmacy*, 508 A.2d 1247, 1253 (Pa. Super. Ct. 1986).

173. *Id.*

174. *Id.* at 1253-54.

175. The *Horner* court agreed. The court stated that "the pharmacist may be in the best position to determine how the medication should be taken to maximize the therapeutic benefit to that patient, to communicate that information to the customer or his physician, and to answer any of the customer's questions regarding consumption of the medication." *Horner v. Spalitto*, 1 S.W.3d 519, 524 (Mo. Ct. App. 1999). The court also found that physicians and patients should "welcome [pharmacists'] insights to help make the dangers of drug therapy safer," *Id.* at 524 n.5, and that the pharmacist's suggestions "should increase the overall quality of health care," *Id.* at 523.

expertise and experience than their physician counterparts.<sup>176</sup> This assumption also rests on shaky ground.

First, pharmacists focus between five and seven years of study on medications, while medical students spend approximately three semesters on pharmaceuticals.<sup>177</sup> Pharmacy students now also have the option of pursuing a higher degree; many schools offer the Doctor of Pharmacy degree, a six-year program intended to "train pharmacists to act as conduits of medical knowledge, professionals educated to counsel customers" in drug use.<sup>178</sup> Pharmacists' education must continue; they are required to take continuing education classes yearly to keep them up to date on new medications.<sup>179</sup> Conversely, physicians are not required to attend pharmaceutical-specific continuing education courses.<sup>180</sup>

The end result of pharmacists' education and experience is that their "knowledge of drugs surpasses that of any other health professional."<sup>181</sup> Certainly, this is not to say that doctors are not qualified to write prescriptions; however, it does suggest that pharmacists have knowledge which may be of assistance in the prescribing process.<sup>182</sup>

Any concerns that courts have had with pharmacists' ability to communicate with customers should be alleviated with the advent of courses regarding communication and counseling that are now included at pharmacy schools nationwide.<sup>183</sup> As mentioned previously, new Doctor of Pharmacy programs stress counseling, and schools have begun to include subjects relating to counseling in their regular curriculum. Some of the new courses were probably created to address the new OBRA counseling requirements for pharmacists.<sup>184</sup>

Within the past ten years there has been an increase in the number of courts and states that have adopted the "modern" view of pharmacists' duties. The tide has turned because those jurisdictions recognize pharmacists' specialized knowledge and experience, knowledge which is of great use in the administration of health care. Pharmacists in general have embraced that standard, the federal

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176. See *supra* notes 41-53 and accompanying text.

177. See Steven W. Huang, *The Omnibus Reconciliation Act of 1990: Redefining Pharmacists' Legal Responsibilities*, 24 AM. J.L. & MED. 417, 441 (1998). Such continuing education courses may be necessary to keep up with the staggering pace at which the Food and Drug Administration ("FDA") is approving new medications. *Id.* (stating that in 1996-98 the FDA approved ninety-two new medications).

178. *Id.* at 440.

179. See Quick, *supra* note 96, at 150.

180. See Huang, *supra* note 177, at 441.

181. Brushwood, *supra* note 98, at 502.

182. See Brushwood, *supra* note 98, at 502 (stating that the pharmacist's role is as gatekeeper, where he or she must "detect indicators of potential problems and contact the prescriber to request clarification").

183. See Quick, *supra* note 96, at 149.

184. See *supra* notes 108-113 and accompanying text.

government has endorsed it, and states have codified it. Now, Missouri is the most recent addition to those jurisdictions that recognize the importance of pharmacists in today's health care system.

Certainly, the *Horner* court recognized that pharmaceutical science has evolved within the last three decades to become just that—a science. Although courts adhering to the traditional approach contend that the difference between pharmacists then and now is slight, the increased education, training, and the new-found “patient-centered” approach to pharmacy show that pharmacists have evolved to consult patients and provide treatment, not to merely fill orders for physicians. To neglect the fact that pharmacists play a large role in today's health care would be to discount the OBRA mandate that pharmacists provide consultation, as well as the professional standards utilized by pharmacists themselves. Instead, the *Horner* court opted to recognize Missouri's pharmacists as members of a true profession that must adhere to the current standards of that profession.

The recent expansion of the practice of pharmacy throughout the country makes it easier for courts that wish to expand the duties of the profession. Patient assessment and consultation require more complex analysis by the pharmacist in general; it follows that a responsibility for the outcome of that consultation would be the pharmacist's.<sup>185</sup>

## VI. CONCLUSION

In *Horner*, the court adopted a new standard for one of Missouri's most respected professions—pharmacists. In so doing, it gave recognition to an expanding science, implicitly understanding the role that pharmacists play in the Missouri public's life. Rather than treating the pharmacist as an order filler, Missouri's new standard treats the pharmacist as an expert in drugs and pharmacology, who necessarily must provide competent health care for an already overworked system.

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185. See Boatwright, *supra* note 118, at 588.